

Patent
Attorney's Docket No. 000500-285

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of)	
)	
Dan HAUZENBERGER)	Group Art Unit: Unassigned
)	
Application No.: Unassigned)	Prior Examiner: Unassigned
)	
Filed: February 21, 2001)	
)	
For: A METHOD FOR MEASURING A)	
PATIENT'S ABILITY TO)	
METABOLIZE CERTAIN DRUGS)	
(as amended))	

INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

In accordance with the duty of disclosure as set forth in 37 C.F.R. § 1.56, applicants hereby submit the following information in conformance with 37 C.F.R. §§ 1.97 and 1.98. Pursuant to 37 C.F.R. § 1.98, a copy of each of the documents cited is enclosed.

The references were cited during the PCT international phase. A copy of the International Search Report is also enclosed.

The documents are being submitted within 3 months of the filing or entry of the national stage of this application or before the first Office Action on the merits, whichever is later, therefore no fee or certification is required under 37 C.F.R. § 1.97(b).

09/763292

02 Rec'd PCT/PTO 21 FEB 2001

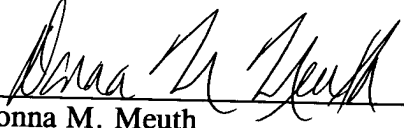
Information Disclosure Statement
Application No. To be assigned
Attorney's Docket No. 000500-285
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To assist the Examiner, the references are listed on the attached form PTO-1449. It is respectfully requested that an Examiner initialed copy of this form be returned to the undersigned.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

By: _____


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Date: February 21, 2001

INTERNATIONAL SEARCH REPORT

International application No.

PCT/SE 99/01449

A. CLASSIFICATION OF SUBJECT MATTER

IPC7: C12Q 1/68, C12Q 1/34, C12N 15/11 // C12N 9/02
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC7: C12Q, C12N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 9530766 A1 (THE SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES), 16 November 1995 (16.11.95), page 40, line 27 - line 35; page 42, line 37; page 45, line 14 - line 16	16
A	--	1-9
A	WO 9113075 A2 (ORION-YHTYMÄ OY), 5 Sept 1991 (05.09.91), especially page 4, line 28 - page 5, line 30 and claims	1-18
	--	

☒ Further documents are listed in the continuation of Box C.☒ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"I" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

21 December 1999

Date of mailing of the international search report

17 January 2000 (17.01.00)

Name and mailing address of the ISA

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/SE 99/01449

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	File WPI, Derwent accession no. 98138246, SRL KK: "Detecting point mutation in exon 4 of human cytochrome P450 2C19 gene - comprises carrying out PCR using specific oligio:nucleotide primers, useful for, e.g. detecting abnormalities in S-mephenytoin metabolism"; & JP,a,10014585, 980120,DW9813 --	8-9
A	Pharmacogenetics, Volume 6, 1996, Michael J. Stubbins et al, ""Genetic analysis of the human cytochrome P450 CYP2C9 locus"" page 429 - page 439 --	10-15,17-18
A	WO 9534679 A2 (THE SECRETARY, DEPARTMENT OF HEALTH AND HUMAN SERVICES), 21 December 1995 (21.12.95) -- -----	10-15,17-18

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 99/01449

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see extra sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 99 01449

According to PCT rule 13.2, an international application shall relate to one invention only or a group of inventions linked by one or more of the same or corresponding "special technical features", i.e., features that define a contribution which each of the inventions, considered as a whole, makes over the prior art.

The application relates to a method and different DNA-sequences (detection primers) from isoforms of cytochrome P450. A special technical feature could be detection primers hybridising immediately adjacent and in 5' in relation to a point mutation in a DNA sequence encoding cytochrome P450 isoforms. However, such primers are contemplated in WO95/30766, see e.g. page 40, lines 30-35. Thus, the claimed invention fails to comply with the demand for unity *a posteriori*.

The following inventions were found:

- Invention 1, claims 1-3: Method for determining the ability of cells in a sample to metabolise certain drugs comprising the steps a)-d) in claim 1.
- Invention 2, claims 4-6: Detection primers derived from the sequence in claim 4.
- Invention 3, claims 7: Detection primers derived from the sequence in claim 7.
- Invention 4, claims 8-9: Detection primers derived from the sequence in claim 8.
- Invention 5, claims 10-11 and 17: Detection primers derived from the sequence in claim 10 and a kit comprising the primers
- Invention 6, claims 12 and 17: Detection primers derived from the sequence in claim 12 and a kit comprising the primers.
- Invention 7, claims 13-14 and 18: Detection primers derived from the sequence in claim 13 and a kit comprising the primers.
- Invention 8, claims 15 and 18: Detection primers derived from the sequence in claim 15 and a kit comprising the primers.
- Invention 9, claim 16: A kit for detecting a possible point mutation in the cytochrome P450 isoform CYP2C19 comprising a detection primer according to claims 4-9.

In spite of the non-unity all inventions has been searched.

INTERNATIONAL SEARCH REPORT
Information on patent family members

02/12/99

International application No.
PCT/SE 99/01449

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9530766 A1	16/11/95	AU 2476695 A US 5912120 A	29/11/95 15/06/99
WO 9113075 A2	05/09/91	AT 180019 T AU 642709 B AU 7235191 A CA 2071537 A DE 648280 T DE 69131233 D,T EP 0648280 A,B SE 0648280 T3 ES 2072235 T FI 102297 B FI 923653 A GR 95300047 T HU 211058 B IL 97222 A JP 2786011 B JP 5504477 T NO 923116 A NZ 237134 A PT 96776 A,B	15/05/99 28/10/93 18/09/91 17/08/91 30/11/95 04/11/99 19/04/95 16/07/95 00/00/00 14/08/92 31/07/95 30/10/95 31/08/95 13/08/98 15/07/93 10/08/92 25/06/92 31/10/91
WO 9534679 A2	21/12/95	AU 2860295 A GB 2303853 A,B GB 9412054 D GB 9502728 D GB 9626479 D US 5891633 A DE 69507636 D,T EP 0795158 A,B PL 320020 A GB 9507640 D	05/01/96 05/03/97 00/00/00 00/00/00 00/00/00 06/04/99 05/08/99 17/09/97 01/09/97 00/00/00